



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Southwest Region
7920 Elmbrook Drive
Suite 102
Dallas, TX 75247-4982

Telephone: 214-655-8100
FAX: 214-655-8130

December 13, 2001

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

02-SWR-WL-16/8

Sabrina Murphy
Assistant Radiology Supervisor
Rose Breast Center
4500 E. 9th Avenue
Suite 130
Denver, CO 80220

RE: Inspection ID – 1344860009

Dear Ms. Murphy,

On 12/5/2001, a representative of the State of Colorado, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

The Mammography Quality Standards Act of 1992 requires your facility to meet specific standards. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

- Level 1: Processor QC records in the month of 07/2001 were missing for at least 30% of operating days, for processor 0000000001, Kodak, RP X-OMAT M6B,6AN,6AW, room darkroom at site Rose Breast Center

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Level 1 findings may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. They represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to:

- Placing your facility under a Directed Plan of Correction.
- Charging your facility for the cost of on-site monitoring.

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- Placing your facilities under a Directed Plan of Correction.
- Charging your facilities for the cost of on-site monitoring.
- Assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspension or revocation of your facilities' FDA certificates, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. You are required to respond to this office in writing within fifteen (15) working days from receipt of this letter. Please address the following:

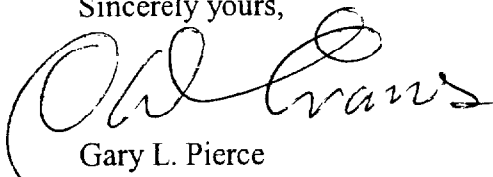
- The specific steps you have taken to correct all of the violations noted in this letter.
- Each step your facilities are taking to prevent the recurrence of similar violations.
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate.
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:
Angela T. Moak, Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, Texas 75247-4982

This letter pertains only to findings of your inspections and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Angela Moak at (214) 655-8100 ext. 135.

Sincerely yours,



Gary L. Pierce
Regional Food and Drug Director

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